

**Remarks/Arguments**

Claims 1-5, 7-14, 16, 17, 20, 22, 23, 25 and 26 are pending in the subject application and are presented for examination on the merits. Claims 1, 20 and 25 have been amended to recite that the amount of protein detected by the claimed methods is greater than the amount of protein detected by radioimmune assay using antibodies to native protein. This amendment is supported by the disclosure at paragraph 75, for example, as well as the examples. Claims 1 and 20 were further amended to define the total protein detected as including native protein and intact modified forms of the protein. This amendment is supported throughout the specification, and is illustrated in several figures, included figures 4-6. Claim 2 was amended to delete the term “drug abuse.” No new matter is added by these amendments to the claims. Claim 7 was amended to delete reference to horse radish peroxidase.

**I. Rejection of Claims 26 and 2 Under 35 U.S.C. § 112, Second Paragraph**

The rejection of claim 26 is respectfully rendered moot by deletion of the claim.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The examiner asserts that the meaning of the term “drug abuse” will vary from expert to expert, rendering the term indefinite.

Applicant respectfully disagrees with the examiner. The term “drug abuse” is well understood within the medical community, as shown by the complete definition provided by Stedman’s Medical Dictionary. However, inasmuch as the term “drug abuse” is encompassed by the broader term “side effect of use of drugs,” which is also a limitation of claim 2, Applicant has deleted the term “drug abuse.” Thus, claim 2 remains directed to a method for detecting the therapeutic effective of a treatment agent for renal disease and/or renal complications of drug abuse; *i.e.*, the side effects of the use of drugs. As such, the scope of claim 2 remains the same.

Accordingly, the rejection of claim 2 under 35 U.S.C. § 112, is respectfully traversed.

**II. Rejection of Claims 1-5, 7-14, 16-17, 20, 22, 23 and 25 Under 35 U.S.C. § 102(b)**

Claims 1-5, 7-14, 16, 17, 20, 22, 23 and 25 stand rejected under 35 U.S.C. § 102(b) as anticipated by Trevisan. The examiner asserts that there is a possibility that Trevisan's antibody to serum albumin (native albumin) may detect some modified intact albumin, and therefore, Trevisan anticipates the present methods.

This rejection is respectfully traversed as follows.

Applicant has shown that proteins in the urine exist in two general forms- the native form (identical to serum protein; immunoreactive) and intact modified form (immuno non-reactive) as defined in the present invention. Applicant has provided evidence that antibodies to serum proteins (native proteins) detect significantly less than the total amount of that protein in the urine. *See* Comper Declaration, September 11, 2002 (of record).

The inventions of claims 1-5, 7, 9-14, 16, 17, 20 and 22, 23 and 25 are directed to methods which rely in part on the detection of total protein in urine, which includes native and intact modified forms of the protein. The amount of total protein detected by the claimed methods is greater than the amount of protein detected by the use of antibodies to serum (native) protein, thus providing a more sensitive assay.

In contrast, Trevisan discloses the use of an antibody to serum albumin and therefore, that antibody does not detect the total amount of albumin present in urine. As such, Trevisan does not anticipate the present claims. Moreover, there is no teaching or suggestion in Trevisan that intact modified forms of protein exist in urine, and therefore, this reference does not render the claimed inventions obvious.

**Application No.: 09/893,346**

Accordingly, the rejection of claims 1-5, 7-14, 16, 17, 20, 22, 23 and 25 under 35 U.S.C. § 102(b) as anticipated by Trevisan is respectfully traversed.

It is respectfully submitted that the present application, as amended above, is in condition for allowance, an early notification thereof being earnestly solicited. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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